

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION
No. 5:18-CV-514-D

AQUESTIVE THERAPEUTICS, INC.,)
)
Plaintiff,)
)
v.)
)
BIODELIVERY SCIENCES)
INTERNATIONAL, INC.,)
)
Defendant.)

ORDER

On January 13, 2017, Aquestive Therapeutics, Inc., f/k/a MonoSol Rx, LLC (“Aquestive” or “plaintiff”), filed a complaint in the United States District Court for the District of New Jersey against BioDelivery Sciences International, Inc. (“BioDelivery” or “defendant”) alleging patent infringement [D.E. 1]. On October 30, 2018, that court transferred the case to this court [D.E. 70, 71]. On November 20, 2018, BioDelivery moved to dismiss Aquestive’s complaint [D.E. 79] and filed a memorandum in support [D.E. 80]. On January 2, 2019, Aquestive responded in opposition [D.E. 87]. On January 16, 2019, BioDelivery replied [D.E. 89]. On November 26, 2018, BioDelivery moved to stay the action pending the United States Patent and Trademark Office’s (“PTO”) inter partes review of the patent at issue [D.E. 83] and filed a memorandum in support [D.E. 84]. On January 7, 2019, Aquestive responded in opposition [D.E. 88]. On January 22, 2019, BioDelivery replied [D.E. 90]. On April 9, 2019, Aquestive filed a sur-reply [D.E. 98]. As explained below, the court grants BioDelivery’s motion to dismiss, denies as moot BioDelivery’s motion to stay, and dismisses the complaint for failure to state a claim.

I.

Aquestive is a pharmaceutical company based in New Jersey that specializes in developing and commercializing “film pharmaceutical and over-the-counter drug products.” Compl. [D.E. 1] ¶¶ 6, 14. Aquestive has obtained over 150 patents. See id. ¶ 14. BioDelivery, which is based in North Carolina, sells various film pharmaceutical products used to deliver drugs, including the allegedly infringing BELBUCA (buprenorphine) buccal film (“BELBUCA”) product. See id. ¶¶ 1–3; [D.E. 1-2]; [D.E. 1-3].

On July 1, 2014, Garry L. Myers, Pradeep Sanghvi, Andrew Philip Verrall, Vimala Francis, and Laura Moss obtained United States Patent No. 8,765,167 (the “‘167 patent”), entitled “Uniform Films for Rapid-Dissolve Dosage Form Incorporating Anti-Tacking Compositions.” See Compl. [D.E. 1] ¶ 15; [D.E. 1-1]. The ‘167 patent concerns “rapidly dissolving films that incorporate anti-tacking agents and/or that contain an active component—such as a drug—that is evenly distributed throughout the film.” Compl. [D.E. 1] ¶ 16; see [D.E. 1-1]. Aquestive alleges that the ‘167 patent discloses “pioneering improvements” that “enable uniform distribution of components” in the film and that “prevent undesired aggregations of components in the final film product.” Compl. [D.E. 1] ¶ 17. See id. Aquestive alleges that it owns all rights, title, and interest in the ‘167 patent. See id. ¶ 18.

BioDelivery markets and sells BELBUCA, a pharmaceutical drug product used to deliver buprenorphine hydrochloride, which is an opioid prescribed to treat acute and chronic pain. See id. ¶¶ 1–3, 21–22; [D.E. 1-2]; [D.E. 1-3]. BioDelivery also sells BUNAVAIL, a pharmaceutical drug product similar to BELBUCA. See Compl. [D.E. 1] ¶ 4. On September 22, 2014, Aquestive sued BioDelivery for patent infringement based on BioDelivery’s BUNAVAIL product. See id. On October 28, 2014, BioDelivery filed four petitions for inter partes review of the ‘167 patent with the

Patent Trial and Appeal Board (“PTAB”). See id. Despite the pending patent infringement suit concerning BUNAVAIL, BioDelivery began to sell BELBUCA. See id. ¶¶ 5, 32–33.

Aquestive alleges that BELBUCA infringes the ‘167 patent. See id. ¶ 25. Specifically, Aquestive alleges that BELBUCA infringes claims 13, 33, 39, 45, 52, 66, 73, 83, 89, 95–98, 100–03, 105, 107–08, and 117–18 of the ‘167 patent. See id. ¶ 28. Aquestive also alleges that it has not granted to any party, including BioDelivery, a license to make, use, sell, or offer for sale BELBUCA. See id. ¶ 29. Moreover, Aquestive alleges that BioDelivery has induced direct infringement of the ‘167 patent by actively encouraging others to make, use, sell, or offer for sale BELBUCA in violation of the claims of the ‘167 patent. See id. ¶¶ 36–37. Aquestive seeks damages, enhanced damages for willful infringement, attorneys’ fees, and a permanent injunction prohibiting BioDelivery from engaging in future infringement of the ‘167 patent. See id. at 9–10.

II.

A motion to dismiss under Rule 12(b)(6) tests the complaint’s legal and factual sufficiency. See Ashcroft v. Iqbal, 556 U.S. 662, 677–80 (2009); Bell Atl. Corp. v. Twombly, 550 U.S. 544, 554–63 (2007); Coleman v. Md. Court of Appeals, 626 F.3d 187, 190 (4th Cir. 2010), aff’d, 566 U.S. 30 (2012); Giarratano v. Johnson, 521 F.3d 298, 302 (4th Cir. 2008).¹ To withstand a Rule 12(b)(6) motion, a pleading “must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” Iqbal, 556 U.S. at 678 (quotation omitted); see Twombly, 550 U.S. at 570; Giarratano, 521 F.3d at 302. In considering the motion, the court must construe the facts and

¹ The court rejects BioDelivery’s argument that Aquestive lacks standing to sue for patent infringement. See, e.g., Alfred E. Mann Found. for Sci. Res. v. Cochlear Corp., 604 F.3d 1354, 1359–63 (Fed. Cir. 2010); Aspex Eyewear, Inc. v. Miracle Optics, Inc., 434 F.3d 1336, 1340–44 (Fed. Cir. 2006); Jasco Prods. Co. v. Prime Wire & Cable, Inc., No. 5:18-CV-44-RJC-DSC, 2018 WL 4576780, at *2 (W.D.N.C. Sept. 6, 2018) (unpublished); [D.E. 80-9].

reasonable inferences “in the light most favorable to the [nonmoving party].” Massey v. Ojaniit, 759 F.3d 343, 352 (4th Cir. 2014) (quotation omitted); see Clatterbuck v. City of Charlottesville, 708 F.3d 549, 557 (4th Cir. 2013), abrogated on other grounds by Reed v. Town of Gilbert, 135 S. Ct. 2218 (2015). A court need not accept as true a complaint’s legal conclusions, “unwarranted inferences, unreasonable conclusions, or arguments.” Giarratano, 521 F.3d at 302 (quotation omitted); see Iqbal, 556 U.S. at 678–79. Rather, a plaintiff’s factual allegations must “nudge[] [its] claims,” Twombly, 550 U.S. at 570, beyond the realm of “mere possibility” into “plausibility.” Iqbal, 556 U.S. at 678–79. Moreover, Iqbal and Twombly apply to patent infringement claims. See Lifetime Indus., Inc. v. Trim-Lok, Inc., 869 F.3d 1372, 1379 (Fed. Cir. 2017); Macronix Int’l Co. v. Spansion Inc., 4 F. Supp. 3d 797, 803 (E.D. Va. 2014); cf. Disc Disease Sols. Inc. v. VGH Sols., Inc., 888 F.3d 1256, 1259 n.3 (Fed. Cir. 2018); Woods v. City of Greensboro, 855 F.3d 639, 647 (4th Cir. 2017).

When evaluating a motion to dismiss, a court considers the pleadings and any materials “attached or incorporated into the complaint.” E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc., 637 F.3d 435, 448 (4th Cir. 2011); see Fed. R. Civ. P. 10(c); Goines v. Valley Cmty. Servs. Bd., 822 F.3d 159, 165–66 (4th Cir. 2016). A court may also consider a document submitted by a moving party if it is “integral to the complaint and there is no dispute about the document’s authenticity.” Goines, 822 F.3d at 166. Additionally, a court may take judicial notice of public records without converting the motion to dismiss into a motion for summary judgment. See, e.g., Fed. R. Evid. 201; Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007); Philips v. Pitt Cty. Mem’l Hosp., 572 F.3d 176, 180 (4th Cir. 2009).

As for Aquestive’s direct infringement claim, whoever “without authority makes, uses, offers to sell, or sells any patented invention . . . infringes the patent.” 35 U.S.C. § 271(a). When

analyzing a direct infringement claim, a court makes two inquiries. First, the court determines the scope and meaning of the patent claims asserted. Second, the court compares those claims to the allegedly infringing product. See N. Am. Container, Inc. v. Plastipak Packaging, Inc., 415 F.3d 1335, 1344 (Fed. Cir. 2005). When analyzing the second issue, the court must determine that every claim limitation or its equivalent is in the accused device. See id.; Carroll Touch, Inc. v. Electro Mech. Sys., Inc., 15 F.3d 1573, 1576 (Fed. Cir. 1993). A complaint that alleges patent infringement must place the “alleged infringer on notice of what activity is being accused of infringement.” Lifetime Indus., Inc., 869 F.3d at 1379 (alteration and quotation omitted); see, e.g., Panduit Corp. v. Corning Inc., No. 5:18-CV-229-FL, 2019 WL 189817, at *3–5 (E.D.N.C. Jan. 14, 2019) (unpublished).

Although Aquestive identifies the specific claims that it alleges that BELBUCA infringes, see Compl. [D.E. 1] ¶¶ 2, 28, Aquestive “does not identify with any particularity how each allegedly infringing feature of the accused product[] infringes any of the” claims at issue. Jenkins v. LogicMark, LLC, No. 3:16-CV-751-HEH, 2017 WL 376154, at *3 (E.D. Va. Jan. 25, 2017) (unpublished); see, e.g., Artrip v. Ball Corp., No. 1:14CV14, 2017 WL 5037470, at *3 (W.D. Va. Nov. 3, 2017) (unpublished); Macronix Int’l. Co., 4 F. Supp. 3d at 804–05. For example, while Aquestive alleges that BELBUCA is sold in different dosage strengths and is a “buccal film providing transmucosal delivery of buprenorphine hydrochloride,” Compl. [D.E. 1] ¶¶ 20–23, Aquestive does not allege how these features of BELBUCA infringe the ‘167 patent. Thus, even viewing the facts and reasonable inferences in the light most favorable to Aquestive, Aquestive’s direct patent infringement is not factually sufficient to state a claim upon which relief can be granted, and the court grants BioDelivery’s motion to dismiss Aquestive’s direct infringement claim.

As for Aquestive’s indirect infringement claim, whoever “actively induces infringement of

a patent shall be liable as an infringer.” 35 U.S.C. § 271(b). A patentee alleging such a claim “has the burden to show direct infringement for each instance of indirect infringement.” DSU Med. Corp. v. JMS Co., 471 F.3d 1293, 1303 (Fed. Cir. 2006); see Limelight Networks, Inc. v. Akamai Techs., Inc., 572 U.S. 915, 917, 922 (2014). Moreover, an indirect infringement claim requires proof of specific intent and action to induce infringement. See Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1364 (Fed. Cir. 2003). The defendant must also have known of the patent and that the induced acts constitute direct patent infringement. See Commil USA, LLC v. Cisco Sys., Inc., 135 S. Ct. 1920, 1926 (2015); Global-Tech Appliances, Inc. v. SEB S.A., 563 U.S. 754, 766 (2011). Although Aquestive alleges that BioDelivery knew of the ‘167 patent and, before January 6, 2017, had licensed production and sale of BELBUCA to a third-party, see Compl. [D.E. 1] ¶¶ 4–5, 19, Aquestive does not plausibly allege either direct infringement or that BioDelivery specifically intended to infringe the ‘167 patent. Thus, the court grants BioDelivery’s motion to dismiss Aquestive’s indirect infringement claim

As for Aquestive’s contributory infringement claim, 35 U.S.C. § 271(c) concerns contributory infringement. It states:

Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

35 U.S.C. § 271(c). “Like induced infringement, contributory infringement requires knowledge of the patent in suit and knowledge of patent infringement.” Commil USA, LLC, 135 S. Ct. at 1926. As with Aquestive’s direct and indirect patent infringement claims, Aquestive’s contributory infringement claim is factually insufficient to state a plausible claim for relief. See Compl. [D.E.

1] ¶ 37. Accordingly, the court grants BioDelivery's motion to dismiss Aquestive's contributory infringement claim.

As for BioDelivery's motion to stay [D.E. 83], the motion is moot because the court grants BioDelivery's motion to dismiss [D.E. 79]. Accordingly, the court denies as moot BioDelivery's motion to stay.

III.

In sum, the court GRANTS BioDelivery's motion to dismiss for failure to state a claim [D.E. 79], DISMISSES without prejudice Aquestive's complaint, and DENIES AS MOOT BioDelivery's motion to stay [D.E. 83].

SO ORDERED. This 6 day of August 2019.

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JAMES C. DEVER III
United States District Judge